



February 01, 2025

**National Stock Exchange of India Limited**

Exchange Plaza,  
Bandra Kurla Complex,  
Bandra (East),  
Mumbai - 400 051

**Symbol: LUPIN**

**BSE Limited**

P. J. Towers, Dalal Street,  
Mumbai Samachar Marg,  
Mumbai - 400 001

**Scrip Code: Equity - 500257**

**Subject: Disclosure pursuant to Regulation 30 of SEBI (Listing Obligations and Disclosure Requirements) Regulations, 2015 ('Listing Regulations').**

***Dear Sir/Madam,***

We are pleased to enclose a Press Release as regards completion of a Pre-Approval Inspection by the U.S. FDA of Edaravone Oral Suspension, 105 mg/ 5 mL at the Company's manufacturing facility in Somerset, New Jersey. The inspection was carried out from January 28 to February 1, 2025, and concluded with zero 483 observations.

The same is for your information and dissemination.

Thanking you,

**For LUPIN LIMITED**

**AMIT KUMAR GUPTA  
COMPANY SECRETARY & COMPLIANCE OFFICER  
(ACS -15754)**

**Encl: a/a.**

LUPIN LIMITED

Registered Office: 3<sup>rd</sup> Floor, Kalpataru Inspire, Off W. E. Highway, Santacruz (East), Mumbai - 400 055 India. Tel: (91-22) 6640 2323.

Corporate Identity Number: L24100MH1983PLC029442

[www.lupin.com](http://www.lupin.com)

## Lupin Announces Closure of Inspection by U.S. FDA at its Somerset Facility with No Observations

**Mumbai, February 1, 2025:** Global pharma major Lupin Limited (Lupin) today announced that the United States Food and Drug Administration (U.S. FDA) has completed a Pre-Approval Inspection (PAI) of Edaravone Oral Suspension, 105 mg/ 5 mL at its manufacturing facility in Somerset, New Jersey. The inspection was carried out from January 28 to February 1, 2025, and concluded with zero 483 observations.

**Nilesh Gupta, Managing Director, Lupin** said, “The successful outcome of the U.S. FDA inspection at our Somerset facility is a testament to our commitment to uphold and maintain the highest standards of quality, compliance and safety across our facilities. We remain steadfast in our mission to improve the lives of our patients globally.”

### About Lupin

Lupin Limited is a global pharmaceutical leader headquartered in Mumbai, India, with products distributed in over 100 markets. Lupin specializes in pharmaceutical products, including branded and generic formulations, complex generics, biotechnology products, and active pharmaceutical ingredients. Trusted by healthcare professionals and consumers globally, the company enjoys a strong position in India and the U.S. across multiple therapy areas, including respiratory, cardiovascular, anti-diabetic, anti-infective, gastrointestinal, central nervous system, and women's health. Lupin has 15 state-of-the-art manufacturing sites and 7 research centers globally, along with a dedicated workforce of over 22,000 professionals. Lupin is committed to improving patient health outcomes through its subsidiaries - Lupin Diagnostics, Lupin Digital Health, and Lupin Manufacturing Solutions. To know more, visit [www.lupin.com](http://www.lupin.com) or follow us on LinkedIn <https://www.linkedin.com/company/lupin>

**For further information or queries please contact –**

**Rajalakshmi Azariah**

Vice President & Global Head – Corporate Communications, Lupin

[rajalakshmi.azariah@lupin.com](mailto:rajalakshmi.azariah@lupin.com)